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For: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

2. (Amended) A [The] method for administering a drug to a subject [method described in claim 1 wherein said dosage form is an osmotic dosage form] comprising:

administering a dosage form to the subject wherein the dosage form comprises:

(a) a longitudinally compressed tablet core [containing] comprising a plurality of layers wherein the drug is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane [wall] surrounding the [said] longitudinally compressed tablet core to thereby forming [form] a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the [said] semipermeable membrane [wall] into the [said] compartment; and

(c) an orifice formed through the [said] semipermeable membrane [wall] and into the [said] longitudinally compressed tablet core to permit drug to be released from within the [said] compartment into the [said] external fluid environment;

wherein the dosage form releases the drug at an ascending release rate for an extended time period.

3. (Amended) The method according to [described in] claim 2, wherein the [said] longitudinally compressed tablet core comprises two layers and the [said] drug is contained within a first layer and the [said] fluid-expandable polymer is contained within a second layer and [further wherein said] the orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent [to] the [said] first layer.

4. (Amended) The method according to [described in] claim 3, wherein the [said] [osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of a drug applied as a coating onto the outer surface of the [said osmotic] dosage form.

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5. **(Amended)** The method according to [described in] claim 2, wherein the [said] longitudinally compressed tablet core comprises three layers and a portion of the [said] drug is contained within a first layer and the remaining portion of the [said] drug is contained within a second layer, wherein the portion [concentration] of drug contained within the [said] first layer is less than the portion [concentration] of drug contained within the [said] second layer, and wherein the [said] fluid-expandable polymer is contained within a third layer and the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent [to said] the first layer.

6. **(Amended)** The method according to [described in] claim 5, wherein the [said osmotic] dosage form further [additionally] comprises an immediate-release dose of a drug applied as a coating onto the outer surface of the [said osmotic] dosage form.

7. **(Amended)** A method for treating ADHD, the method comprising [the step of] orally administering a longitudinally compressed tablet dosage form containing a CNS-acting drug in a pharmaceutically acceptable carrier wherein the [said] dosage form releases the [said] CNS-acting drug from the [said] dosage form at an ascending release rate for an extended time period.

8. **(Amended)** The method according to [described in] claim 7, wherein the [said] CNS-acting drug is a CNS-stimulant drug selected from the group consisting of methylphenidate, d-threo-methylphenidate, amphetamine, dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.

9. **(Amended)** The method according to [described in] claim 8, wherein the [said] CNS-stimulant drug is methylphenidate.

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10. (Amended) The method according to [described in] claim 9, wherein the [said] dosage form comprises: [is an osmotic dosage form comprising]

(a) a longitudinally compressed tablet core containing a plurality of layers wherein methylphenidate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane [wall] surrounding the [said] longitudinally compressed tablet core to [thereby] form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the [said] semipermeable membrane [wall] into the [said] compartment; and

(c) an orifice formed through the [said] semipermeable membrane [wall] and into the [said] longitudinally compressed tablet core to permit methylphenidate to be released from [within said] the compartment into the [said] external fluid environment.

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11. (Amended) The method according to [described in] claim 10, wherein the [said] longitudinally compressed tablet core comprises two layers and the [said] methylphenidate is contained within a first layer and the [said] fluid-expandable polymer is contained within a second layer and further wherein the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent to the [said] first layer.

12. (Amended) The method according to [described in] claim 11, wherein the [said osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of methylphenidate applied as a coating onto the outer surface of the [said osmotic] dosage form.

13. (Amended) The method according to [described in] claim 10, wherein the [said] longitudinally compressed tablet core comprises three layers and a portion of the [said] methylphenidate is contained within a first layer and the remaining portion of the [said] methylphenidate is contained within a second layer, wherein the portion [concentration] of

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methylphenidate contained within the [said] first layer is less than the portion concentration of methylphenidate contained within said second layer, and wherein the [said] fluid-expandable polymer is contained within a third layer and the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent the [to said] first layer.

14. (Amended) The method according to [described in] claim 13, wherein the [said osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of methylphenidate applied as a coating onto the outer surface of the [said osmotic] dosage form.

15. (Amended) A method for [effectively] treating ADHD [for a prolonged therapy period of at least about 10 hours] comprising administering [methylphenidate in] a dosage form comprising methylphenidate that provides release of methylphenidate at an ascending release rate over an extended time period.

16. (Amended) A method [for providing plasma methylphenidate concentrations that are substantially smoothly ascending over an extended time period] comprising administering methylphenidate in a longitudinally compressed tablet dosage form that provides release of methylphenidate at an ascending release rate over an extended time period and further provides plasma methylphenidate concentrations that are substantially smoothly ascending over an extended time period

17. (Amended) A longitudinally compressed tablet dosage form comprising a drug in a pharmaceutically acceptable carrier wherein[, following oral administration, said] the dosage form releases the [said] drug from the [said] dosage form at an ascending release rate for an extended time period following oral administration to a subject.

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18. (Amended) A [The] dosage form [described in claim 17 wherein said dosage form is an osmotic dosage form] comprising:

(a) a longitudinally compressed tablet core containing a plurality of layers wherein a [said] drug is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane [wall] surrounding the [said] longitudinally compressed tablet core to [thereby] form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the [said] semipermeable membrane [wall] into the [said] compartment; and

(c) an orifice formed through the [said] semipermeable membrane [wall] and into the [said] longitudinally compressed tablet core to permit the drug to be released from within the [said] compartment and into the [said] external fluid environment.

21 B1 19. (Amended) The dosage form according to [described in] claim 18, wherein the [said] longitudinally compressed tablet core comprises two layers and the [said] drug is contained within a first layer and the [said] fluid-expandable polymer is contained within a second layer and further wherein the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent the [to said] first layer.

20. (Amended) The dosage form according to [described in] claim 19, wherein the [said osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of a drug applied as a coating onto the outer surface of said osmotic dosage form.

21. (Amended) The dosage form according to [described in] claim 18, wherein the [said] longitudinally compressed tablet core comprises three layers and a portion of the [said] drug is contained within a first layer and the remaining portion of the [said] drug is contained within a second layer, wherein the portion [concentration] of drug contained within the [said] first layer is

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less than the portion [concentration] of drug contained within the [said] second layer, and wherein the [said] fluid-expandable polymer is contained within a third layer and the [said] orifice is formed through said semipermeable membrane [wall at a location] adjacent to the [said] first layer.

22. **(Amended)** The dosage form according to [described in] claim 21, wherein the [said osmotic] dosage form additionally comprises an outer surface having an immediate-release dose of a drug applied as a coating onto the outer surface of the [said osmotic] dosage form.

23. **(Amended)** A longitudinally compressed tablet dosage form containing a CNS-acting drug in a pharmaceutically acceptable carrier wherein the [said] dosage form, following oral administration to a subject, releases the [said] CNS-acting drug from the [said] dosage form at an ascending release rate for an extended time period.

24. **(Amended)** The dosage form according to [described in] claim 23, wherein the [said] CNS-acting drug is a CNS-stimulant drug selected from the group consisting of methylphenidate, d-threo-methylphenidate, amphetamine, dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.

25. **(Amended)** The dosage form according to [described in] claim 24, wherein the [said] CNS-stimulant drug is methylphenidate.

26. **(Amended)** The dosage form according to [described in] claim 25 [wherein said dosage form is an osmotic dosage form] comprising:

- (a) a longitudinally compressed tablet core containing a plurality of layers wherein methylphenidate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

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(b) a semipermeable membrane [wall] surrounding the [said] longitudinally compressed tablet core to [thereby] form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the [said] semipermeable membrane [wall] into the [said] compartment; and

(c) an orifice formed through the [said] semipermeable membrane [wall] and into the [said] longitudinally compressed tablet core to permit methylphenidate to be released from within the [said] compartment into the [said] external fluid environment.

27. (Amended) The dosage form according to [described in] claim 26, wherein the [said] longitudinally compressed tablet core comprises two layers and the [said] methylphenidate is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent the [to said] first layer.

28. (Amended) The dosage form according to [described in] claim 27, wherein the [said osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of methylphenidate applied as a coating onto the outer surface of the [said osmotic] dosage form.

29. (Amended) The dosage form according to [described in] claim 26, wherein the [said] longitudinally compressed tablet core comprises three layers and a portion of the [said] methylphenidate is contained within a first layer and the remaining portion of the [said] methylphenidate is contained within a second layer, wherein the portion [concentration] of methylphenidate contained within the [said] first layer is less than the portion [concentration] of methylphenidate contained within the [said] second layer, and wherein the [said] fluid-expandable polymer is contained within a third layer and the [said] orifice is formed through the [said] semipermeable membrane [wall at a location] adjacent the [to said] first layer.

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30. (Amended) The dosage form according to [described in] claim 29, wherein the [said osmotic] dosage form further [additionally] comprises an outer surface having an immediate-release dose of methylphenidate applied as a coating onto the outer surface of the [said osmotic] dosage form.

31. (Amended) The dosage form according to [described in] claim 30, wherein the [said] coating comprises an antidegradation agent.

32. (Amended) The dosage form according to [described in] claim 31, wherein the [said] antidegradation agent is phosphoric acid.

33. (Amended) The dosage form according to [described in] claim 29, wherein the [said] semipermeable membrane comprises cellulose acetate and a flux-enhancing agent.

34. (Amended) The dosage form according to [described in] claim 33, wherein the [said] flux-enhancing agent is a copolymer of ethylene and propylene oxide.

35. (New) An oral dosage form comprising a drug and a pharmaceutically acceptable carrier comprising:

- (a) a capsule shaped osmotically active tablet core comprising at least one drug containing layer and a push layer wherein the push layer comprises a suitable fluid expandable polymer;
- (b) a semipermeable membrane surrounding the capsule shaped osmotically active tablet core to form a compartment; and
- (c) an orifice formed through the semipermeable membrane and into the capsule shaped osmotically active tablet core at a location adjacent the at least one

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drug layer to permit the drug to be released from within the compartment into the external fluid environment in response to osmotic passage of fluid into the capsule shaped osmotically active tablet core, wherein the dosage form releases the drug at an ascending release rate for an extended time period.

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36. (New) The dosage form according to claim ⁷⁵~~35~~, wherein the dosage form further comprises a drug layer overcoat.

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37. (New) The dosage form according to claim ⁷⁵~~35~~, wherein the push layer further comprises at least one osmagent.

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38. (New) The dosage form according to claim ⁷⁵~~35~~, wherein the dosage form is a bi-layer dosage form comprising one drug layer and a push layer.

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39. (New) The dosage form according to claim ⁷⁸~~38~~, wherein the bi-layer dosage form achieves an ascending release rate for an extended time period of at least 50% of a T₉₀ period.

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40. (New) The dosage form according to claim ⁷⁸~~38~~, wherein at least about 35% of the push layer comprises the osmagent.

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41. (New) The dosage form according to claim ⁸⁰~~40~~, wherein the osmagent is sodium chloride.

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42. (New) The dosage form according to claim ⁷⁸~~38~~, wherein the dosage form further comprises an outer surface and an immediate-release dosage of the drug applied as a coating onto the outer surface.

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~~43~~. (New) The dosage form according to claim ⁷⁸~~38~~, wherein the drug layer comprises methylphenidate or a pharmaceutically acceptable salt thereof.

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~~44~~. (New) The dosage form according to claim ⁸⁰~~40~~, wherein the coating comprises an antidegradation agent.

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~~45~~. (New) The dosage form according to claim ⁸⁴~~44~~, wherein the antidegradation agent is phosphoric acid.

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~~46~~. (New) The dosage form according to claim ⁸³~~43~~, wherein the semipermeable membrane further comprises cellulose acetate and a flux-enhancing agent.

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~~47~~. (New) The dosage form according to claim ⁸⁶~~46~~, wherein the flux-enhancing agent is a copolymer of ethylene and propylene oxide.

Remarks

Claims 1-34 having been amended, claims 35-47 having been added, the claims pending in the above-identified patent application are claims 1-47. Claims 1-34 have been amended to more clearly define Applicants' invention. Support for these amendments can be found, for example, in the claims as originally filed and in the specification at page 7, lines 3-21. Support for new claims 35-47 can be found, for example, in the claims as originally filed and in the specification at page 7, lines 3-21, page 18, lines 11-13, and at page 19, lines 8-13.

In amending the above claims, Applicants are not acquiescing to objections or rejections asserted by the Examiner. Applicants have amended the claims to further the prosecution of this application and retain the right to file divisional or continuing applications to claim any canceled subject matter.